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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,575	07/05/2001	Jan Zur Megede	PP01631.102 (CHIR-1631/03	1709

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,575	MEGEDE ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-97 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-97 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice Seq. Compliance*.

DETAILED ACTION

Claims 1-97 are pending.

This application contains sequence disclosures that are encompassed by the definition for nucleotide sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements for Patent Applications Containing Nucleotide Sequence Disclosures.

Table 4, page 107, lines 14-25 contains nucleotide sequences that are not listed in the CRF.

A complete response to the instant office action must include a response to the sequence compliance notification.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 13, 14, 59-73 and 97, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOs: 30-32, 62, and 103, classifiable in class 435, subclass 320.1.

II. Claims 2-6 and 38-46, drawn to an expression cassette comprising a polynucleotide of SEQ ID NOs: 46, 119-127, and 131-133, classifiable in class 435, subclass 320.1.

III. Claims 7 and 8, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 51 and 99, classifiable in class 435, subclass 320.1.

IV. Claims 9 and 10, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 55, 57, 96, 101, and 134-135, classifiable in class 435, subclass 320.1.

V. Claims 11, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 58, classifiable in class 435, subclass 320.1.

VI. Claims 12, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 60, classifiable in class 435, subclass 320.1.

VII. Claim 15, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 64 and 66, classifiable in class 435, subclass 320.1.

VIII. Claims 16 and 17, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 68 and 70, classifiable in class 435, subclass 320.1.

IX. Claims 18-21, 33, 34, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 72, 74, 91, 105, and 107, classifiable in class 435, subclass 320.1.

X. Claims 22 and 23, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 76 and 78, classifiable in class 435, subclass 320.1.

XI. Claims 24-26, 35, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 80, 81, 83, 93, 94, 109, 111, and 113, classifiable in class 435, subclass 320.1.

XII. Claim 27, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 85 and 113, classifiable in class 435, subclass 320.1.

XIII. Claims 28 and 29, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 87 and 115, classifiable in class 435, subclass 320.1.

XIV. Claims 30-32, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 89 and 117, classifiable in class 435, subclass 320.1.

XV. Claims 36-37, drawn to an expression cassette comprising a polynucleotide of SEQ ID NO: 96, classifiable in class 435, subclass 320.1.

XVI. Claims 47-51, drawn to a polynucleotide depicted in SEQ ID NO: 33, classifiable in class 536, subclass 23.1.

XVII. Claims 52-56 and 74-77, drawn to a polynucleotide depicted in SEQ ID NO: 45, classifiable in class 536, subclass 23.1.

XVIII. Claims 57-58, drawn to a polynucleotide depicted in SEQ ID NO: 128, classifiable in class 536, subclass 23.1.

XIX. Claims 78-90 and 92-96, drawn to a method of DNA immunization in a subject or generating an immune response in a subject, classifiable in class 424, subclass 93.2.

XX. Claim 91, drawn to a method of generating an immune response in a subject using an HIV polypeptide, classifiable in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XVIII are patentable distinct products.

The polynucleotides of Groups I-XVIII are patentably distinct inventions for the following reasons: The polynucleotides in Groups I-XVIII have a different function and different effect. Furthermore, the information provided by any of the polynucleotides of group I can be used to make a materially different polypeptide than the polypeptide encoded by the polynucleotides in groups II-XVIII and vice versa. In addition, a sequence having 90% sequence identity to a sequence presented in Group I encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with a polynucleotide in Groups II-XVIII and vice versa. In addition, the polynucleotides that fall within the scope of Group I cannot be made by methods for producing the polynucleotides of Groups II-XVIII and vice versa. Furthermore, searching the inventions of groups I-XVIII together would impose a serious search burden. In the instant case, the search of the polynucleotides in Groups I-XVIII are not coextensive. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of a sequence in Groups I-XVIII there may be journal articles devoted solely to the polynucleotides of one Group, which would not describe the polynucleotides in any other group. Searching, therefore is not coextensive. In addition, the polynucleotide claims include polypeptides having 70% identity to the polypeptide encoded by the polynucleotide sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. Furthermore, a search of the polynucleotide

molecule of some Groups, e.g., Group I (claim 2), Group IV (claim 9), Group IX (claim 20) would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polynucleotide of any other group not encompassing these sequences. As such, it would be burdensome to search the inventions of Groups I-XVIII together.

Inventions XIX and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of DNA immunization (group XIX) and the method of producing an immune response to recombinant proteins (group XX) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for DNA immunization differ significantly for each of the materials. For DNA immunization, a mammal may be used. For producing recombinant proteins for use in vivo, in vitro prokaryotic cells may be used. Therefore, each method is divergent in materials and steps. For these reasons the Inventions of XIX and XX are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The invention of Groups XIX and XX has a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups XIX and XX together.

Invention I and Inventions XIX and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the expression cassette of Group I can be used to make recombinant proteins as in Group XX as opposed to its use in a DNA immunization method in Group XIX.

Searching the inventions of Groups I and XIX and XX together would impose serious search burden. The inventions of Groups I and XIX and XX have a separate search status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the method of DNA immunization and method of recombinant proteins are not coextensive. Group I encompasses molecules which are claimed in terms of sequence identity in regard to SEQ ID NOs: 30-32, which are not required for the search of either Group XIX or Group XX. In contrast, the search for group XIX or XX would require a text search for the method of DNA immunization in addition to polynucleotide search of sequences with 90% sequence identity of SEQ ID NOs: 30-32. Prior art which teaches a polynucleotide that has 90% sequence identity of SEQ ID NOs: 30-32 would not necessarily be applicable to the method of using sequences having at least 90% sequence identity of SEQ ID NOs: 30-32. Moreover, even if the polynucleotides were known, the method of DNA immunization or producing recombinant proteins using the product may be novel and unobvious in view of the preamble or active steps.

Inventions II-XVIII and either Inventions XIX or XX are unrelated because the product of groups II-XVIII is not used or otherwise involved in the process of group XIX or XX.

Because these inventions are distinct for the reasons given above, have acquired a separate search status in the art as shown by their different classifications, and the search required for each Group is not required for the other Groups because each group requires a different non-patent literature search due to each group comprising different products and/or methods steps, restriction for examination purposes as indicated is proper.

In addition, if applicants elect from Groups I-IV and VII-XIV, a further restriction is required because the groups detailed above read on patentably distinct sequences.

It is noted that this is a restriction requirement to a single sequence and **NOT** a species election requirement.

If applicants elect Group I: applicants are required to elect from SEQ ID NOs: 30, 31, 32, 62, and 103. The sequences encode HIV Pol polypeptides.

If applicants elect Group II: applicants are required to elect from SEQ ID NOs: 46, 119-127, 131, 132, and 133. The sequences encode HIV Env polypeptides.

If applicants elect Group III: applicants are required to elect from SEQ ID NOs: 51 and 99. The sequences encode HIV Gag polypeptides.

If applicants elect Group IV: applicants are required to elect from SEQ ID NOs: 55, 57, 96, 101, 134 and 135. The sequences encode HIV Nef polypeptides.

If applicants elect Group VII: applicants are required to elect from SEQ ID NOs: 64 and 66. The sequences encode HIV Prot polypeptides.

If applicants elect Group VIII: applicants are required to elect from SEQ ID NOs: 68 and 70. The sequences encode HIV Prot/RT polypeptides.

If applicants elect Group IX: applicants are required to elect from SEQ ID NOs: 72, 74, 91, 105 and 107. The sequences encode HIV Rev polypeptides.

If applicants elect Group X: applicants are required to elect from SEQ ID NOs: 76 and 78. The sequences encode HIV RT polypeptides.

If applicants elect Group XI: applicants are required to elect from SEQ ID NOs: 80, 81, 83, 93, 109, 111, and 113. The sequences encode HIV Tat polypeptides.

If applicants elect Group XII: applicants are required to elect from SEQ ID NOs: 85 and 113. The sequences encode HIV Vif polypeptides.

If applicants elect Group XIII: applicants are required to elect from SEQ ID NOs: 87 and 115. The sequences encode HIV Vpr polypeptides.

If applicants elect Group XIV: applicants are required to elect from SEQ ID NOs: 89 and 117. The sequences encode HIV Vpu polypeptides.

There are no claims encompassing a generic HIV polypeptide, which indicates that the SEQ ID NOs are independent and there is no disclosure of relationship (percent sequence identity) in the specification between the claimed sequences in each group.

In addition, it has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER

Application No.: 09/899,575

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicants attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a Sequence Listing as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the Sequence Listing in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the ASequence Listing in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up ARaw Sequence Listing.

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the Sequence Listing is not the same as the computer readable from of the Sequence Listing as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Sequences on page 107 are missing from the CRF.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the ASequence Listing.

☒ An initial or substitute paper copy of the Sequence Listing, as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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